JUL 17 2003

K030403
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APPENDIX I. 510(K) SUMMARY

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the CEFAR Medical AB summary for the CEFAR REHAB 2 and REHAB 2 PRO:

SUBMITTER'S NAME:	CEFAR Medical AB
ADDRESS:	Scheelevagen 19A SE-223 70 Lund Sweden
CONTACT PERSON:	Constance Bundy
TELEPHONE NUMBER:	763-574-1976
FAX NUMBER:	763-571-2437
DATE OF SUBMISSION:	February 4, 2003

1. **Identification of device**
   Proprietary Name: CEFAR REHAB 2 and REHAB 2 PRO
   Common Name: Powered muscle stimulator
   Classification Status: Class II per regulations 890.5850
   Product Codes: IPF

2. **Equivalent devices**
   CEFAR Medical AB believes the CEFAR REHAB 2 and REHAB 2 PRO is substantially equivalent to:

Powered Muscle Stimulator	Ortho DX	Rehabilicare	K971542

3. **Description of the Device**
   The CEFAR REHAB 2 and CEFAR REHAB 2 PRO are battery powered handheld Neuro-Muscular Electrical Stimulation (NMES) devices only to be used under medical supervision for adjunctive therapy of medical diseases and conditions. The devices operate with two channels and 22 preset stimulation programs. On the CEFAR REHAB 2 PRO the user also can set parameters to create user defined stimulation programs.

   Program information and amplitude is displayed on a LCD. The user can set the amplitude in the range 0-100 mA for all programs.

4. **Intended use**
   The CEFAR REHAB 2 and CEFAR REHAB 2 PRO are symmetrical biphasic neuromuscular electronic stimulators indicated for use under medical supervision for adjunctive therapy in the treatment of medical diseases and conditions. Intended uses include:

   - Relaxation of muscle spasms
   - Prevention or retardation of disuse atrophy
   - Increasing local blood circulation
   - Muscle re-education
   - Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
   - Maintaining or increasing range of motion

5. **Comparison to predicate device.**

Comparison table

Characteristic	Ortho DX (Predicate device)	CEFAR REHAB 2 and CEFAR REHAB 2 PRO
Indications for use statement	Identical	See *Section 1 B Indications for Use Statement*
Prescription device	Yes	Yes
Number of channels	2	2
Output	0-100 mA	0-100 mA
Wave form	Symmetrical biphasic rectangle with zero net DC	Symmetrical biphasic rectangle with zero net DC
Pulse width	0-300 μs	50-300 μs
Maximum charge per pulse	30 μC	30 μC
Pulse rate	33.3 Hz, fixed	2-120 Hz, fixed in each preset program
Transcutaneous current delivery	Yes, through electrodes placed on patients body	Yes, through electrodes placed on patients body
User control of output	Yes, knobs	Yes, pushbuttons
Power supply	Yes, battery operated 4xAA batteries (rechargeable or alkaline)	Yes, battery operated 2xAA batteries (rechargeable or alkaline)

6. **Discussion of functional and safety testing.**

An extensive collection of tests has been conducted and successfully completed, including system validation in-house and external testing to show compliance with IEC EN 60 601-1-2 regarding EMC, IEC EN 60601-1 regarding general safety for medical equipment.

Notified body SEMKO AB, with ID 0413, has performed the external testing.

7. **Conclusion**

Based on extensive performance testing and a comparison to the predicate device, it is the conclusion of CEFAR Medical AB that the CEFAR REHAB 2 and CEFAR REHAB 2 PRO are substantially equivalent to devices already on the marked (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2003

CEFAR Medical AB
c/o Ms. Constance G. Bundy
C.G. Bundy Associates, Inc.
6740 Riverview Terrace
Minneapolis, MN 55432

Re: K030403
Trade/Device Name: CEFAR REHAB 2 and CEFAR REHAB 2 PRO
Regulation Numbers: 21 CFR 890.5850
Regulation Names: Powered muscle stimulator
Regulatory Class: II
Product Codes: IPF
Dated: May 7, 2003
Received: May 12, 2003

Dear Ms. Bundy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.B. Indications for Use

510(k) Number K030403

Device Name: CEFAR REHAB 2 and CEFAR REHAB 2 PRO

Indications for Use:
The CEFAR REHAB 2 and CEFAR REHAB 2 PRO are symmetrical biphasic neuromuscular electronic stimulators indicated for use under medical supervision for adjunctive therapy in the treatment of medical diseases and conditions. Intended uses include:

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Maintaining or increasing range of motion

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over the Counter Use_____
(Per 21 CFR 801.109)

for Mark N Milhern
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K030403